REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000

(Version 4.1, 4/22/02; FDA/CVM, HFV-230, www.fda.gov/cvm/forms/forms.html)

FEI # (*required*):

Firm (Legal) Name: _____ Date Inspection Ended: _____

Firm (Physical) Address: _____ Lead Investigator: _____

Firm City: _____ Lead Affiliation (***check one***):

❑ Federal

Firm State: _____ ZIP Code: _____ Phone #: _____ ❑ State Agency, (*name*) _____

FDA District Office (***required***): _____

Name and title of person interviewed: _____

Inspection Conclusion: (***Check only one***) ❑ RTC ❑ NAI ❑ CI ❑ Inactive ❑ Out of Business

[**Read Instructions**] [**FORM IS COMPLETED!**] **[Skip ALL Sections!]**

Section 1 – Complete for ALL firms

1. **a)** Type of firm inspected? (***Check all that apply***)

❑ Renderer	❑ FDA Licensed Feed Mill	❑ On-farm Feed Mixer
❑ Protein Blender	❑ Non-FDA Licensed Feed Mill	❑ Feeder of Ruminants
❑ Transporter (Hauler)	❑ Pet Food Manufacturer	❑ Feeder of Ruminants **and** Other Species
❑ Distributor/Retailer	❑ Animal Feed/Pet Food Salvager	❑ Other: _____

b) Does the firm handle feed ingredients or feeds that are intended for the feeding of ruminant animals? ❑ YES ❑ NO

2. Does the firm receive feed ingredients or feeds that contain or may contain prohibited material (with the exception of pet food sold or are intended for sale at retail and laboratory animal feed)? ❑ Retail Pet/Lab Feed Only ❑ YES ❑ NO

a) If "**NO**," check all of the following that describe any safeguards the firm has in place to assure they do not receive prohibited material.

- ❑ Assurance from supplier that they no longer manufacture any products containing prohibited materials
- ❑ Labeling review of incoming materials
- ❑ Use only vegetable source proteins
- ❑ Uses pure animal proteins only from exempted sources (examples: such as porcine, equine, poultry, fish, gelatin)
- ❑ Other, (please describe) _____

_____

[If Feeder of Ruminants (with or without Other Species), SKIP to Section 3;
Otherwise, FORM IS COMPLETED - Skip ALL Remaining Sections!]

b) If "**YES or Retail Pet/Lab Feed Only**," is imported (not originating in the United States) prohibited material used? ❑ YES ❑ NO ❑ Unknown

Please list the country/ies of origin for the imported prohibited material, _____

3. Does the firm receive prohibited material for further distribution **ONLY**? ❑ YES ❑ NO

4. Does the firm manufacture or process products containing prohibited materials? ❑ YES ❑ NO

5. Are the received feed ingredients or feeds containing prohibited materials (referred to in **#2** above) labeled with the caution statement, "**Do not feed to cattle or other ruminants**" (with the exception of pet food sold or are intended for sale at retail and laboratory animal feed)? ❑ Renderer Only ❑ Retail Pet/Lab Feed Only ❑ YES ❑ NO

(continued)

Section 2 – Complete for ALL firm types EXCEPT: Firms that are ONLY described as "Other" Firm Type OR Firms that are ONLY Feeders of Ruminants (with or without Other Species)

6. Are the outgoing feed ingredients or feeds containing prohibited materials labeled with the caution statement, "**Do not feed to cattle or other ruminants**" (with the exception of pet food sold at retail and laboratory animal feed)?

❑ No Outgoing Ingredients/Feeds ❑ Retail Pet/Lab Feed Only ❑ YES ❑ NO

7. Does the firm maintain records sufficient to track the prohibited materials throughout their receipt, processing and distribution, specifically:

a)	Date of receipt **or** purchase **or** sale **or** delivery	❑ YES	❑ NO
b)	Name and address of the seller	❑ YES	❑ NO
c)	Name and address of the consignee	❑ YES	❑ NO
d)	Identification of the product	❑ YES	❑ NO
e)	Quantity	❑ YES	❑ NO
f)	Copies are available for inspection and copying	❑ YES	❑ NO
g)	Are **ONLY** retail cash sales involved?	❑ YES	❑ NO

8. Does the firm manufacture, process, blend and distribute **BOTH** products containing prohibited materials **AND** products containing **only** non-prohibited materials? ❑ YES ❑ NO

9. **a)** If the answer to **#8** is "**NO**," then **SKIP to Question #10**.

If the answer to **#8** is "**YES**," does the firm have a system in place to avoid commingling and cross-contamination?

❑ YES ❑ NO

b) Check all of the following that describe the separation system or clean-out processes and any procedures to avoid commingling and cross-contamination (with the exception of pet food sold at retail and laboratory animal feed).

❑ Sequencing of feeds
❑ Flushing the system, (*please describe*) _____
❑ Written sequencing and flushing procedures
❑ Documentation maintained of sequencing and flushing
❑ Flushed materials discarded or tagged with the caution statement
❑ Physical clean-out (e.g. vacuuming, cleaning)
❑ Dedicated equipment used for prohibited materials
❑ Other, (*please describe*) _____

_____

10. Please describe any additional safeguards the firm has in place to assure that outgoing feed ingredients or feeds containing prohibited material are not shipped to ruminant feeders, _____

(If None, please Enter "None") _____

Section 3 – Complete for ALL Feeders of Ruminants (with or without Other Species)

11. Are ruminant feeders doing the following?

a)	Observing the caution statement on feeds containing prohibited material	❑ YES	❑ NO	❑ No PM-feeds on premises
b)	Maintaining copies of labeling for feeds containing animal protein (**AP**)	❑ YES	❑ NO	❑ No AP-feeds on premises
c)	Maintaining copies of purchase invoices for feeds containing animal protein	❑ YES	❑ NO	❑ No AP-feeds on premises

Section 4 – Complete for ALL firm types

12. **a)** Check all deviations that were noted at the time of inspection. ❑ Commingling ❑ Labeling ❑ No Deviations Noted ❑ Recordkeeping ❑ Feeding Ruminants Prohibited Material

b) If any deviations were noted above, describe commitments made to correct each deviation,

_____

_____

_____

13. Are you attaching any further descriptions or any exhibits or records and/or labeling? ❑ YES ❑ NO

CHANGES from Version 3.1

- **Lead Affiliation** - Includes a description for any State Agency that acts as the lead investigator. Information required for improved program monitoring.
- **Question 1b** - A new question that was not part of any previous checklist versions. Information needed for improved program monitoring.
- **Question 2** - Answers now include the option "Retail Pet/lab Feed Only" for more logical use.
- **Question 2a** - Directions revised to "If Feeder of Ruminant (with or without Other Species)" for better clarification.
- **Questions 2b, 4a** - The question previously contained in Question 4a was moved to Question 2b for better flow. Question 2b (previously Question 4a) revised to include "Retail Pet/Lab Feed Only" for better clarification.
- **Question 5** - Answers now include the options, "Renderer Only" and "Retail Pet/Lab Feed Only" for more logical use.
- **Section 2** - Directions revised to "If Feeder of Ruminant (with or without Other Species)" for better clarification.
- **Question 6** - Answers now include the option "Retail Pet/lab Feed Only" for more logical use.
- **Question 8** - Question revised to "manufacture, process, blend and distribute" to more accurately represent 21 CFR 589.2000(e)(1). Note that firms must manufacture AND distribute both products described in order to be considered for the **YES** response. Distributor/retailer or transporter/hauler firm types that are not additionally involved in the manufacture of animal feeds should be noted with the **No** response.
- **Question 9a** - Question revised from "adequate system" to "system" for better clarification.
- **Question 9b** - "Flushing the system" response additionally asks for a description of the flushing process. Information needed for improved program monitoring.
- **Question 10** - Question includes directions to record "None" if no additional safeguards are in place, other than what might be recorded in previous questions. The added directions remove the ambiguity associated with the question being left blank.
- **Section 4** - Substantial changes have been made and are described below.
- **Question 12** - Previous Questions 12 and 13 have been revised into Questions 12a and 12b. Question 12a asks for all deviations that have been encountered during the inspection, regardless of whether the firm corrected the deviations at the time of inspection or made promises to correct the deviations. If no deviations were noted during the inspection, the answer "No Deviations Noted" should be recorded. Question 12b asks for a description of all corrections or commitments made to correct each deviation noted in Question 12a. Revisions needed for improved program monitoring.
- **Question 13** - Previous Question 14 has been re-numbered to Question 13.

INSTRUCTIONS – For the Lead Investigator

BSE Coordinator. The FDA BSE District Coordinator is responsible for communicating and receiving information related to the BSE Checklist. Questions, comments and concerns should be directed to this individual. All completed BSE Checklists should be mailed **only** to the BSE District Coordinator, and not to CVM.

BSE Checklist Version. Please make sure that you are using the most current BSE Checklist. The version date is located at the top of the form. Check with your BSE Coordinator or the FDA/CVM website (www.fda.gov/cvm/form/forms.html) to make sure that you are using the most recent version. The use of any other version will not be compatible with the BSE Checklist Database and may invalidate the information that you collect.

BSE Checklist Alterations. Some agencies may need to alter the BSE Checklist to better fit their own operations. While CVM does not necessarily object to such alterations, all changes must be added to the end of the form. No additions, deletions or revisions should be made to the main body of the CVM-version of the BSE Checklist.

Legibility. Illegible writing results in inaccurate data, which compromises the BSE Compliance Program. If at all possible, type in your responses. If handwritten, please print letters rather than using longhand.

Completing Sections. Sections should be fully completed for each of the firm types indicated in the header of each Section. Sections that are inappropriately skipped (based on the firm type) will cause the BSE Checklist to be considered incomplete and unacceptable for submission to the Districts.

Completing Questions. The BSE Checklist instructions and flow of questions must be followed. Blank or unanswered required questions will cause the BSE Checklist to be considered incomplete and unacceptable for submission to the Districts.

Descriptive Fields. For those questions that ask for an explanation or description, please be brief and capture the essential elements with as few words as possible. If you feel that certain answers require a more lengthy description, please consider recording the answer on a separate page, which should be attached to the BSE Checklist and so noted in **Question 13**.

Form Is Completed. The instruction "Form Is Completed" means that the investigator needs NOT fill in anymore of the BSE Checklist. Ignore all remaining sections, including Section 4.

FEI Number. The FEI number is absolutely required. You may need to contact your BSE District Coordinator for this information.

Firm Name. Firm names should be consistent with the FDA FACTS database. "Doing Business As" (DBA) names are unacceptable.

Firm Address. The address should reflect the physical location of the firm's activities. Post Office Box numbers are unacceptable.

Inspection Conclusion. This code represents the investigator's reported conclusion and is generally recorded in the FDA FACTS database. You many need to consult with your BSE Coordinator. **RTC** = Referred to Center; **NAI** = No Action Indicated; **CI** = Correction Indicated. Forms should be completed for **Inactive** firms since they might begin production at any time. **Out of Business** firms require no more information gathering.

Firm Type. Please understand the firm type categories provided and use these categories whenever applicable.

Considerations:

- A single firm can be categorized as one or more firm types.
- The BSE Checklist may not fully describe the activities of certain multiple firm type combinations. Please contact your BSE District Coordinator if additional guidance is needed.
- Feed mills should be described on the basis of FDA licensure and NOT on whether the firm produces medicated feeds.
- Ruminant feeders (e.g. dairy farms) might also be On-farm Mixers.
- On-farm Mixers might not be ruminant feeders (e.g. swine farms).
- On-farm Mixers, regardless of the species being fed, are subject to the requirements of the BSE regulation.
- On-farm Mixing applies to mixing that is not performed for the purpose of commercial distribution. Generally the use of on-farm mixed feeds is limited to the same farm premises and so requires minimal controls. However, on-farm mixed feeds that are utilized off-premises and/or outside the direct supervision of the farm manager (e.g., a farm where mixed feeds are delivered for feeding at physically different farm locations, perhaps under a contract arrangement) should be produced under all control measures required by the BSE regulation.
- The "Other" category should be used only for firm operations that are not described by the other categories. Improper use of the "Other" category may cause inaccurate and/or inadequate information to be collected in the remaining Sections.

Feed Ingredients and Feeds. This category refers to substances that are either utilized the manufacture of animal feeds or that are intended to be feed to animals. Substances intended solely for other purposes (e.g. fertilizers) are not included in this category.

Question 11a. Please keep in mind that potential sources of prohibited materials also include pet foods and salvaged pet foods.

INSTRUCTIONS – For the BSE District Coordinator

The BSE District Coordinator has a key role and overall responsibility for ensuring that BSE Checklists are completed fully and accurately, which is vital to the success of BSE compliance efforts. The BSE District Coordinator should pay particular attention to ensuring the following:

- Familiarity with the Instructions for the Lead Investigator.
- The most recent version of the BSE Checklist and accompanying instructions are distributed and utilized.
- The BSE Checklist has not been unacceptably altered.
- All required sections are completed. All questions within a required section are completed.
- Handwritten forms are legible.
- The FEI number is provided
- The FDA District Office identity is provided.
- The Inspection Conclusion is provided.
- Response inconsistencies are resolved.

All completed BSE Checklists should be sent **only** to the BSE District Coordinator, and not to CVM. The Districts will have the responsibility for checking the forms for completeness and accuracy, and for entering the information into FACTS.

Any questions, concerns or comments regarding the BSE Checklist or the BSE Compliance Program should be directed to the appropriate BSE District Coordinator. The following individuals are additional BSE Compliance Program contacts:

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